UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,000	10/04/2005	Hiroko Yanaga	1752-0173PUS1	6374

2292 7590 12/21/2006
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
GOUGH, TIFFANY MAUREEN	
ART UNIT	PAPER NUMBER
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,000	YANAGA, HIROKO	
	Examiner	Art Unit	
	Tiffany M. Gough	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/02,21,27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and response filed 08/21/2006 has been received and entered into the case. Claims 1-4 are pending and have been considered on the merits. Claims 5,6 have been cancelled by applicant. All arguments and amendments have been considered.

The IDS's submitted 6/2,21 and 27/2006 and Translations of Foreign Papers dated 6/6/2006 have been received, entered and considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 and therefore it's dependent claims, 2-4, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the amendment "...wherein no exogenous feeder cells are present in the culture" introduces new matter, which is not described in the specification as originally filed. Applicant states on p.2 of the specification that co-culturing chondrocytes with perichondrial cells in the chondrogenic stage serve as feeder cells to support the proliferation of chondrocytes. Further, applicant merely makes mentions on p.3 of the specification, of nonhuman animal feeder cells, not exogenous feeder cells,

and no where in the specification does applicant make mention of the term "exogenous feeder cells." Exogenous is defined as "from outside the system," which, in relation to the present invention could be cells from anywhere, cells outside of human, outside of the chondrocyte tissue source. It is not clear and there is no support for what exogenous means with regards to applicant's invention. Therefore, "...wherein no exogenous feeder cells are present in the culture" changes the scope of the claims and applicants invention for which no support is provided. **This is a new matter rejection.**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method of producing human chondrocytes comprising co-culturing chondrocytes obtained from cartilage having perichondrium together with the perichondrium. It is therefore confusing what the claims encompass. The claim is interpreted to state "...having perichondrium together with the chondrocytes."

Applicant's amendment to clarify the invention comprising co-culturing the chondrocytes with the perichondrium has been considered and therefore the 112 2nd rejection of record has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiroko et al (WO 02/012451 A1, see English language equivalent Hiroko et al, EP1331264A1). Applicant claims a method of producing human chondrocytes, preferably auricular chondrocytes, from cartilage together with the perichondrium comprising growing cells either as a monolayer or multilayer seeding to give a chondrocyte mass.

Hiroko et al (WO 02/012451 A1, see equivalent EP1331264A1) disclose a method of co-culturing human chondrocytes together with perichondrial cells to produce large amounts of human chondrocytes in culture and further multilayer seeding to give to obtain a chondrocyte mass. Hiroko teaches utilization of a cartilage matrix containing collagen and a cartilage therapy material incorporating their chondrocyte mass. The human chondrocytes used in the invention may be any cartilage tissue such as auricular, costal, articular, intervertebral, or tracheal cartilage, especially auricular, costal and articular cartilage (see EP1331246A1 p.3 lines 18-20).

The previous rejection is maintained. Although, the rejection of record was originally applied as a 102(a) rejection, in light of the new matter added by

amendment, for which there is no support in any priority documents, this rejection is now applied as a 102(b) rejection.

Applicant argues that the reference does not teach co-culturing the chondrocytes with the perichondrium obtained from the same tissue and without any exogenous feeder cells. Applicant states that the feeder cells used in Hiroko's invention are exogenous and can be problematic once transplanted.

However, these arguments fail to be persuasive because although it is not disclosed that the chondrocytes cultured in the Hiroko reference as co-cultured with the pericondrium from which the cells were isolated, human auricular cartilage is known to be coated with pericondrium (see Merriam and Webster online dictionary), thus the chondrocytes isolated by the disclosed method must essentially be coated with the perichondrium and therefore co-cultured together with the perichondrium of the cartilage from which it was isolated. Further, without the support or definition as to what is encompassed by "exogenous feeder cells", the perichondrial cells used in the Hiroko reference are not considered to be "exogenous." Thus, the reference anticipates the claimed subject matter and the claims therefore **remain rejected** over the Hiroko reference.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Klein-Nulend et al (Tissue Engineering, vol 4, 1998).

Applicant claims a method of producing human chondrocytes by co-culturing chondrocytes together with the pericondrium, wherein no exogenous feeder cells are

present in culture. The cartilage tissue from which the chondrocytes are isolated from is preferably auricular cartilage.

Klein-Nulend teach culturing human auricular perichondrium containing chondrocytes, wherein no exogenous feeder cells are present in culture (see Materials and Methods section,p.306 and Results section, p.308-310).

Thus, the reference anticipates the claimed subject matter.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Osch et al (Plastic and Recondtructive Surgery, 2001).

Applicant claims a method of producing human chondrocytes by co-culturing chondrocytes together with the pericondrium, wherein no exogenous feeder cells are present in culture. The culture is seeded to form a monolayer to give a chondrocyte mass . The cartilage tissue from which the chondrocytes are isolated from is preferably auricular cartilage.

Van Osch teach isolating human auricular cartilage and culturing the isolated chondrocytes in a monolayer for 3-4 passages (see Materials and Mthods section, p. 434). The human cells were also seeded into alginate (see Results section, p. 435). No exogenous feeder cells are present in culture.

Although the reference does not necessarily teach the chondrocytes to be co-cultured with the pericondrium, human auricular cartilage is known to be coated with pericondrium, thus the chondrocytes isolated by the disclosed method must essentially

be coated with the perichondrium and therefore co-cultured together with the perichondrium of the cartilage from which it was isolated.

Therefore, the reference anticipates the claimed subject matter.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Larson et al (Matrix Biology, 2002).

Applicant claims a method of producing human chondrocytes by co-culturing chondrocytes together with the pericondrium, wherein no exogenous feeder cells are present in culture.

Larson et al teach producing human chondrocytes by co-culturing chondrocytes with their pericellular matrix attached and no exogeneous feeder cells were added to the culture.

Thus, the reference anticipates the claimed subject matter.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RUTH DAVIS
PRIMARY EXAMINER

Tiffany Gough